a) providing the apparatus of claim 38;

b) positioning the apparatus at a selected location within the passageway; and

c) deploying at least a portion of anchoring members against the inner surface of the passageway thereby anchoring the tubular element within the passageway at the selected location.

46. The apparatus of claim 38, where the anchoring members are substantially oval in cross-section.

47. The apparatus of claim 38, where the anchoring members have a top portion and the top portion is substantially flat.

60. (New) The apparatus of claim 28, where the tubular element is a catheter.

61. (New) The apparatus of claim 28, where the deployment means further comprises a guide wire having a proximal end and a distal end, and where the inner lumen is a collar member attached to the distal end of the guide wire.

62. (New) The apparatus of claim 28, where the anchoring members comprise a pseudoelastic material.

REMARKS

Attached hereto is an APPENDIX SHOWING CHANGES MADE which shows the amendments made to the application. Deletions have been stricken out and insertions have been underlined.

Claims 1, 2, 7 to 11, 22, 24 to 28, 32 to 47, and 60 to 62 are pending in this application. All of the claims stand rejected in a final Office action mailed on July 16, 2002. A Notice of Appeal was filed and an appeal brief submitted. In the appeal brief, Applicant attempted to correct claim 28, which was unintentionally truncated, and claims 29 to 31 which were unintentionally deleted in a response and amendment filed on March 26, 2001. In response to an objection to the appeal brief by the Examiner, Applicant is hereby filing a request for continued examination and this preliminary amendment to correct the claims.

Pursuant to 37 C.F.R. §1.114(d), Applicant intends for this Request for Continued Examination and Preliminary Amendment to withdraw the appeal and to reopen prosecution of the application.

Claim 28 has been amended to remedy an inadvertent error in the response and amendment filed on March 26, 2001. Likewise claims 60 to 62 have been added to replace original claims 29 to 31 which were inadvertently deleted in the response and amendment filed on March 26, 2001. In view of the amendment to claim 28 and in view of the following remarks, Applicant submits that this application is in condition for allowance. Accordingly, reconsideration and a timely indication of allowance are respectfully requested.

In the Final Office action mailed on July 16, 2002, the Examiner rejected claims 1, 2, 11 and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cathcart et al. (U.S. Patent No. 5,681,347). The Examiner contends that Cathcart et al. discloses a device 10 comprising a tubular element 13 comprising a hollow tubular lumen, a deployment element 17, and a plurality of resilient anchoring members 24 attached to the distal end of the inner lumen as claimed. The Examiner states the that word "attached" means to join or connect. The Examiner then goes on to state that the word "join" is being used as "to put into close association or relationship" according to the Webster's II Dictionary.

Appellants submit that the Examiner's rejection is fatally defective, because Cathcart et al. does not teach or suggest the limitation of claim 1 of "a plurality of resilient anchoring members attached to the distal end of the inner lumen." Words in claims are to be given their ordinary meaning in the absence of indication in the application to the contrary. Gentex Corp v. Donnelly Corp., 69 F.3d 527, 530, 36 USPQ2d 1667, 1669 (Fed. Cir. 1995). Courts frequently look to dictionaries to determine ordinary meaning. Sage Products Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1430-1431, 44 USPQ2d 1103, 1113 (Fed. Cir. 1997). Applicant respectfully submits that the ordinary meaning of "attach" is "to cause to adhere; to tie, bind or fasten; as to attach one thing to another by a string, by glue, etc." as defined in the Webster's New Twentieth Century Dictionary, 2nd Ed., ©1983 by Simon and Schuster, New

York, New York, 10020.

The ordinary meaning submitted by Applicant is consistent with the specification which states on page 16, line 16 to page 17, line 8, that the anchoring members may be attached to the deployment means by various methods known in the art, depending on what material the anchoring members and deployment means are comprised of. Listed methods to create attachment to the deployment means include welding, soldering press-fitting, crimping, swedging, epoxy, laser welding and mounting. The attachment of the anchoring means to the distal end of the inner lumen allows the resilient anchoring members to be reversibly moveable by the deployment element.

Cathcart et al. teaches a catheter for deploying a vena cava filter. As seen from Figs. 2, 4, and 5 and from the specification at Col. 5, line 57 to Col. 6, line 2 of Cathcart et al.,

> a cup shaped portion 21 engages a proximal end 22 of a device 23, such as a vena cava filter, having radially extending penetrating or hook portions 24 disposed within the inner portion of the metal segment 20. . . Displacement of the inner member 17 distally relative to the outer member 13 moves the cup shaped portion 21 from the first position depicted in FIG. 3 through a second position depicted in FIG. 4 to a third position depicted in FIG. 5 in which the cup shaped portion 21 distally extends beyond the distal end 15 of the filter 23 and deploys in a patient's lumen.

If the device 23 were attached to cup shaped portion 21, then the device 23 could not deploy in a patent's lumen. Thus, although the device 23 engages the cup shaped portion 21, the device, and its "extending penetrating or hook portions 24" are not "attached to the distal end of the inner lumen" as required by claim 1.

Moreover, Applicants submit that Cathcart et al. does not teach or suggest the limitation of claim 1 that "each anchoring member [is] reversibly moveable by the deployment element between a first position and a second position." As explained above, the penetrating or hook portions 24 taught by Cathcart et al. are part of a deployable device 23. Cathcart et

al. does not provide a means for pulling the deployable device 23 back inside of the catheter once deployed. Thus, Cathcart et al. does not teach or suggest all of the limitations of claim 1.

Cathcart et al. is directed to a catheter for deploying a vena cava filter, not to anchoring a catheter within a passageway formed in a mammalian body to perform measurements. Applicants respectfully submit that one skilled in the art would have no motivation to modify Cathcart et al. to teach the limitations of claim 1 that "a plurality of resilient anchoring members [are] attached to the distal end of the inner lumen" and "each anchoring member [is] reversibly moveable by the deployment element between a first position and a second position."

Therefore, Applicants respectfully submit that claim 1 is novel and nonobvious over Cathcart et al. Claims 2, 7 to 11, 22, and 24 to 27 depend from claim 1 and by definition contain all of the limitations of claim 1. Therefore, claims 2, 7 to 11, 22, and 24 to 27 are patentable over Cathcart et al. for the same reasons that claim 1 is patentable over Cathcart et al.

The Examiner rejected claims 1, 2, 7, 10, 11 and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by Goldberg et al. (U.S. Patent No. 5,152,777). Specifically, the Examiner alleges that Goldberg discloses a device having a tubular element 70, 72, 74 with a hollow tubular lumen, a deployment element 60, 90, 92, and a plurality of resilient anchoring members 32a-f as claimed.

Applicants submit that the Examiner's rejection is fatally defective, because Goldberg et al. does not teach or suggest the limitation of claim 1 that the deployment element has an inner lumen, and that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end." As explained in the application on page 11, the inner lumen of the deployment element allows liquids to be transported through the bore to the passageway site, and devices, such as a transducer, to be inserted and used at the site.

Like Cathcart et al., Goldberg et al. is directed to a blood vessel filter (trap) delivery system. Like Cathcart et al., there is nothing in Goldberg et al., that addresses the problem of

how to anchor a sensing device at a specific location within a passageway of a mammalian patient. Goldberg et al. does not teach or suggest an anchoring system using an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end.

As explained in Col. 7, lines 43 to 63 of Goldberg et al., the trap has a stem 60; the stem 60 has a proximal end 90. To introduce the trap to the appropriate location, the proximal end of the stem is threaded onto an extension stem 92. The trap, stem and extension stem are drawn into an introducer/remover apparatus. Applicants submit that the extension stem 92 is part of the deployment device. As explained at Col. 7, lines 53-56 and shown in Fig. 5A, the trap stem 90 is threaded at 94 to receive trap extension stem 92 having mating threaded end 96. Applicants respectfully submit that the innermost passageway is blocked at the junction of elements 94 and 96. Therefore, Goldberg does not teach or suggest a deployment element having "a bore extending completely through the inner lumen from the proximal end to the distal end."

As explained above, Goldberg et al. is directed to a catheter for deploying a filter, not to anchoring a catheter within a passageway formed in a mammalian body to perform measurements. Applicants respectfully submit that one skilled in the art would have no motivation to modify Goldberg et al. to teach the limitation of claim 1 that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end."

Thus, Applicants submit that claim 1 is novel and nonobvious over Goldberg et al. Claims 2, 7 to 11, 22, and 24 to 27 all depend from claim 1 and by definition contain all of the limitations of claim 1. Therefore, claims 2, 7 to 11, 22, and 24 to 27 are patentable over Goldberg et al. for the same reason that claim 1 is patentable over Goldberg et al.

The Examiner rejected claims 38 to 40, 44 and 45 under 35 U.S.C. § 102(e) as allegedly being anticipated by Hayashi (U.S. Patent No. 5,910,144). Specifically, the Examiner states that Hayashi discloses a prosthesis gripping system comprising a tubular

element 20, 26 comprising a hollow tubular lumen, a deployment element 50, and a plurality of resilient anchoring members 40 as claimed. Applicants submit that Hayashi does not teach or suggest the limitation of claim 38 that the deployment element has an inner lumen and that, "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end."

The Hayashi reference teaches a prosthesis gripping system for enabling the manipulation of a prosthesis deployed or implanted at a repair site.[1] As is the case with the Cathcart et al. and the Goldberg et al. references, the Hayashi reference is not directed to the problem of how to locate a sensor at a specific location within the passageway of a mammalian patient. Therefore, it is not surprising that Hayashi fails to teach the use of an inner lumen having "a bore extending completely through the inner lumen from the proximal end to the distal end."

Hayashi teaches a tubular element 20, 26 having a channel 24.[2] Applicants submit that the channel 24 corresponds to the hollow tubular outer lumen in claim 38. A wire 36 extends through the channel 24.[3] In one embodiment of Hayashi, elements 40 for gripping a prosthesis are attached directly to the end of the wire.[4] In another embodiment of Hayashi a tube 50 is secured to the distal end of the wire, and extends about the secured ends 42 of elements 40 to crimp the joint between wire 36 and secured ends of elements 40.[5] Applicants respectfully submit that the wire is the deployment means and that the wire does not have a bore. Applicants also respectfully submit that even if the tube 50 is considered to be the deployment means, the crimping of the tube 50 to form the joint between the wire 36 and the secured ends

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[1]*See*, Hayashi, Col. 3, lines 34-38.

[2]*See*, Hayashi, Col. 3, lines 59-63.

[3]*See*, Hayashi, Col. 4, lines 4-7.

[4]*See*, Hayashi, Col. 4, lines 11-14.

[5]*See*, Hayashi, Col. 4, lines 26-29.

42 of elements 40 necessarily closes off the proximal end of the tube 50.

Accordingly, Hayashi fails to teach or suggest the use of an inner lumen having "a bore extending completely through the inner lumen from the proximal end to the distal end." Thus, Hayashi does not teach or suggest all of the limitations of claim 38.

As explained above, Hayashi is directed to a prosthesis gripping system for enabling the manipulation of a prosthesis deployed or implanted at a repair site, not to anchoring a catheter within a passageway formed in a mammalian body to perform measurements. Appellants respectfully submit that one skilled in the art would have no motivation to modify Hayashi to teach the limitation of claim 38 that "the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end."

Thus, Applicants submit that claim 38 is novel and nonobvious over Hayashi. Claims 39, 40, 44 and 45 all depend from claim 38 and by definition contain all of the limitations of claim 38. Therefore, claims 39, 40, 44 and 45 are patentable over Hayashi for the same reason that claim 38 is patentable over Hayashi.

The Examiner rejected claims 8 to 10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cathcart et al. in view of Hayman et al. (U.S. Patent No. 5,267,960) and Abrams (U.S. Patent No. 5,492,119). The Examiner has also rejected claims 8, 9, and 26 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. in view of Abrams (U.S. Patent No. 5,492,119). The Examiner has also rejected claims 27 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. in view of Lefebvre (U.S. Patent No. 5,938,683). The Examiner has also rejected claims 24, 25, 28 to 30 and 33 to 36 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. in view of Hayashi. The Examiner has also rejected claims 37 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goldberg et al. in view of Hayashi in further view of Lefebvre (U.S. Patent No. 5,938,683). The Examiner has also rejected claim 47 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hayashi in view of Lefebvre (U.S. Patent No. 5,938,683).

All of the rejections under 35 U.S.C. § 103 are based principally upon either Cathcart

et al., Goldberg et al. or Hayashi. As explained above, none of these three references are directed to the problem of how to specifically locate a sensing device within the passageway of a mammalian patient. Accordingly, none of these three primary references discloses or fairly suggests, in any way, a method of anchoring a catheter having an inner lumen through which a sensing device can be transported, i.e., an inner lumen having a bore which extends "completely through the inner lumen from the proximal end to the distal end." Moreover, nothing in any of the secondary references discloses or suggests this very important feature of the invention.

Accordingly, since no combination of any of the references cited in this application disclose or fairly suggest the use of an inner lumen having a bore extending from its distal end to its proximal end, there is no basis for deeming obvious any of the claims in this application. No individual of ordinary skill in the art, having knowledge of the references cited in the application, would have found it obvious to provide the unique anchoring system of the invention, including the use of an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end. Accordingly, all rejections under 35 U.S.C. § 103 should be withdrawn and no additional rejections of other claims based upon 35 U.S.C. § 103 should be applied.

In view of the above amendments and remarks, Applicants respectfully submit that this application is in condition for allowance. Reconsideration and a timely indication of allowance is therefore respectfully requested.

Please deduct all fees associated with this communication, including the fees for the added claims, from Deposit Account No. 19-2090.

Respectfully submitted,

SHELDON & MAK PC

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APPENDIX SHOWING CHANGES MADE

28. (Twice Amended) An apparatus for anchoring a tubular element within a passageway formed in a mammalian body, the passageway having a wall with an inner surface, the apparatus comprising:

a) a tubular element comprising a hollow tubular outer lumen having a proximal end and a distal end;

b) a deployment ~~element comprise a pseudoelastic material~~ means positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end; and,

c) a plurality of resilient anchoring members attached within the wall of the inner lumen and extending longitudinally beyond the distal end of the inner lumen, each anchoring member being reversibly movable by the deployment means between a first position and a second position, where in the first position, at least a portion of each anchoring member is retracted within the outer lumen, and where in the second position, at least a portion of each anchoring member is deployed exteriorly to the outer lumen, so as to engage the inner surface of the mammalian passageway and anchor the tubular element in the passageway.